Justification for the selection of a candidate CoRAP substance

**Substance Name (Public Name):** Diethyl phthalate

**Chemical Group:**

**EC Number:** 201-550-6

**CAS Number:** 84-66-2

**Submitted by:** Germany/Portugal

**Published:** 20/03/2013

**NOTE**

This document has been prepared by the evaluating Member State given in the CoRAP update.
Contents

1 IDENTITY OF THE SUBSTANCE  
   1.1 Name and other identifiers of the substance  3

2 CLASSIFICATION AND LABELLING  
   2.1 Harmonised Classification in Annex VI of the CLP  4
   2.2 Proposal for Harmonised Classification in Annex VI of the CLP  4
   2.3 Self classification  4

3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE  
   3.1 Legal basis for the proposal  4
   3.2 Grounds for concern  5
   3.3 Information on aggregated tonnage and uses  6
   3.4 Other completed/ongoing regulatory processes that may affect suitability  
       for substance evaluation  7
   3.5 Information to be requested to clarify the suspected risk  8
   3.6 Potential follow-up and link to risk management  8
# 1 IDENTITY OF THE SUBSTANCE

## 1.1 Name and other identifiers of the substance

<table>
<thead>
<tr>
<th>Table 1: Substance identity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Public Name:</strong></td>
</tr>
<tr>
<td><strong>EC number:</strong></td>
</tr>
<tr>
<td><strong>EC name:</strong></td>
</tr>
<tr>
<td><strong>CAS number (in the EC inventory):</strong></td>
</tr>
<tr>
<td><strong>CAS number:</strong></td>
</tr>
<tr>
<td><strong>CAS name:</strong></td>
</tr>
<tr>
<td><strong>IUPAC name:</strong></td>
</tr>
<tr>
<td><strong>Index number in Annex VI of the CLP Regulation:</strong></td>
</tr>
<tr>
<td><strong>Molecular formula:</strong></td>
</tr>
<tr>
<td><strong>Molecular weight or molecular weight range:</strong></td>
</tr>
<tr>
<td><strong>Synonyms:</strong></td>
</tr>
</tbody>
</table>

**Type of substance**  
- [ ] Mono-constituent  
- [ ] Multi-constituent  
- [ ] UVCB

**Structural formula:**

![Structural formula of Diethyl phthalate](image)
2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP
Diethyl phthalate is not listed in Annex VI of the CLP.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP
No proposal for harmonised classification in Annex VI of the CLP has been submitted.

2.3 Self classification
Not classified by registrants.

Notified classifications to “Classification and Labelling Inventory” according to CLP criteria:
- Acute Tox. 3; H331: Toxic if inhaled.
- STOT RE 2; H373: May cause damage to organs.
- Eye Irrit. 2 ; H319 : Causes serious eye irritation.
- Skin Irrit. 2 ; H315 : Causes skin irritation.
- Acute Tox. 4; H332: Harmful if inhaled.
- STOT SE 3; H335: May cause respiratory irritation.
- Repr. 2 ; H361: Suspected of damaging fertility or the unborn child.

Different notifications can be found in the inventory for DEP. The above listed notifications comprise all endpoints for which notifications have been made.

3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

3.1 Legal basis for the proposal
- Article 44(1) (refined prioritisation criteria for substance evaluation)
- Article 45(5) (Member State priority)
3.2 Grounds for concern

(a) Health effects

Endocrine Disrupter: Information from databases:

<table>
<thead>
<tr>
<th>EC Endocrine Substances Database</th>
<th>Conclusion: Clear Evidence of ED effects Human Health: CAT1 Wildlife CAT3b</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA Endocrine Screening Database</td>
<td>Potential for Androgen Receptor Binding/Species: Rat/Structure: DDT/Assay: AR Binding (Receptor Binding Assay)</td>
</tr>
</tbody>
</table>

**Endocrine Disrupter:**

**Oestrogenic activity** weak in recombinant yeast assay (Harris et al. 1997),\(^1\) increased proliferation of human breast cancer MCF-7 cells (Hong et al. 2005).\(^2\)

**Acute toxicity:** Dermal \(LD_{50} = 1118\) mg/kg (Acute tox., Cat 4)

**Repeated dose toxicity:** Oral – rat, 16 wk study (1978), NOAEL 150 mg/kg/day, LOAEL 750 mg/kg/day (reduced body weight), rat (Wistar), 150 day study (Pereira et al. 2008),\(^3\) LOAEL 0.57 mg/kg/day (reduced body weight, testis weights, epididymis weight).

Dermal – mouse (B6C6F1), rat (Fisher 344/N), NTP (2001) 28 day study, administration 5/7 days, NOAEL mouse/rat ~450/368 mg/kg/day (adjusted 321/262 mg/kg), LOAEL mouse/rat 750/736 (adjusted 536/526 mg/kg) mg/kg/day (increased liver weight/increase liver and kidney weight)

**Reproduction:** Developmental toxicity (1992): diet exposure gestation day 6-15, Maternal NOAEL 200 mg/kg/day; Developmental NOAEL 1910 mg/kg/day (supernumery ribs).

---


**Fertility:** Two-generation study (2005, rat) NOAEL (P, F1 parents) 1016-1297 mg/kg (197-267 mg/kg increased abnormal sperm),\(^4\) NOAEL (F1, F2 pups) 222-267 mg/kg; additional studies NTP two-generation study (2000, mouse) and One-generation study (1989, rat). Mice study (NTP) indicates moderate effects in F2 (sperm parameters also affected). DEP had no effect on F0 reproductive performance, while producing moderate reproductive effects in the second generation in the presence of mild body weight gain inhibitions and moderate increases in liver weight.

(b) Wide and dispersive use, consumer and worker exposure

DEP has a wide dispersive use (worker/professional and consumer uses). According to the information on the registration data dissemination website, DEP is present in various products for consumer uses e.g. air care products, washing and cleaning products, personal care products, polishes and wax blends. It is also in coatings and paints, thinners, paint removes, fillers, putties, plasters, modelling clay and in plastic articles.

DEP is added as a solvent for fragrances in a various common consumer products e.g. air fresheners as aerosol sprays or continuously emitting liquids, washing and cleaning products, toys, etc. One intention for substance evaluation is to scrutinize if the exposure is acceptable/under controlled conditions.

### 3.3 Information on aggregated tonnage and uses

<table>
<thead>
<tr>
<th>☐ 1 – 10 tpa</th>
<th>☐ 10 – 100 tpa</th>
<th>☐ 100 – 1000 tpa</th>
</tr>
</thead>
<tbody>
<tr>
<td>☒ 1000 – 10,000 tpa</td>
<td>☐ 10,000 – 100,000 tpa</td>
<td></td>
</tr>
<tr>
<td>☐ 100,000 – 1000,000 tpa</td>
<td>☐ &gt; 1000,000 tpa</td>
<td></td>
</tr>
</tbody>
</table>

☐ Confidential

Note: In-addition to the above mentioned tonnage band, another registration identified intermediate use of the substance, for which the tonnage band is not disseminated.

---

DEP has wide and dispersive uses by workers/professionals and consumers.

The substance is part of disperse dye and plastic plasters and used for denaturation of perfume alcohols and as fixing agent (GESTIS-database on hazardous substances, 2011).\(^5\)

According to the information on the “ECHA registration data dissemination website” DEP is registered as constituent for the following consumer uses:

- PC 3: Air care products
- PC 21: Laboratory chemicals
- PC 28: Perfumes, fragrances
- PC 29: Pharmaceuticals
- PC 35: Washing and cleaning products (including solvent based products)
- PC 39: Cosmetics, personal care products
- PC 9a: Coatings and paints, thinners, paint removes
- PC 9b: Fillers, putties, plasters, modelling clay
- PC 31: Polishes and wax blends

### 3.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

<table>
<thead>
<tr>
<th>Compliance check final</th>
<th>Dangerous substances Directive 67/548/EEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testing proposal</td>
<td>Existing Substances Regulation 793/93/EEC</td>
</tr>
<tr>
<td>Annex VI (CLP)</td>
<td>Plant Protection Products Regulation 91/414/EEC</td>
</tr>
<tr>
<td>Annex XIV (Authorisation)</td>
<td>Other (provide further details below)</td>
</tr>
<tr>
<td>Annex XVII (Restriction)</td>
<td></td>
</tr>
</tbody>
</table>

*Please provide further details*


---

EC no. 201-550-6 MSCA – Germany Page 7 of 8
### 3.5 Information to be requested to clarify the suspected risk

| ☒ Information on toxicological properties | ☐ Information on physico-chemical properties |
| ☐ Information on fate and behaviour | ☒ Information on exposure |
| ☐ Information on ecotoxicological properties | ☒ Information on uses |
| ☐ Other (provide further details below) | |

Investigation of potential for endocrine disruption and more detailed information on adverse effects on male reproductive system is needed.

Information related to consumer products and identified consumer uses are needed to refine exposure assessments.

### 3.6 Potential follow-up and link to risk management

| ☐ Restriction | ☐ Harmonised C&L | ☐ Authorisation | ☐ Other (provide further details) |
| ☐ | | | |

The substance evaluation will be performed with an open outcome. The most appropriate follow-up measure can not be predicted so far.